

A Business Plan To Help The ‘Global South’ In Its Fight Against Neglected Diseases

Biotechnology companies operating in the world’s emerging economies are developing solutions to these local problems.

by Sarah E. Frew, Victor Y. Liu, and Peter A. Singer

ABSTRACT: Although neglected tropical diseases (NTDs) threaten the health of those living in the developing world, innovation directed toward addressing NTDs is comparatively meager. Health biotechnology firms in rapidly growing economies in the global South are developing and selling vaccines, diagnostics, and therapeutics for these diseases to local markets. In this paper we identify a pipeline of sixty-two NTD products from seventy-eight “Southern” companies. We also propose creation of a Global Health Accelerator—a new nonprofit organization whose mission would be to support and help grow this Southern source of affordable innovation for NTDs. [Health Aff (Millwood). 2009;28(6):1760–73]

NEGLECTED TROPICAL DISEASES (NTDs) are a major health problem for the poor. They affect at least one billion people in the developing world, including 400 million children, and cause significant illness and death.¹ The most conservative definition of NTDs includes thirteen parasitic and bacterial infections: three soil-transmitted helminth infections (ascariasis, hookworm, and trichuriasis), lymphatic filariasis, onchocerciasis, dracunculiasis, schistosomiasis, Chagas disease, human African trypanosomiasis, leishmaniasis, Buruli ulcer, leprosy, and trachoma.² A more expansive definition of NTDs from the journal *PLoS Neglected Tropical Diseases* also includes dengue fever, the treponematoses, leptospirosis, strongyloidiasis, foodborne trematodiasis, neurocysticercosis, scabies, and other tropical infections. For this paper, we use the latter definition of NTDs. We also use the term “neglected diseases” to refer to the NTDs plus HIV, malaria, and TB. Regardless of the definition used, NTDs are chronic infectious diseases

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that disproportionately affect those living in rural and poor urban areas in low- and middle-income countries. NTDs promote poverty by disabling and stigmatizing patients and by adversely affecting child health and development, pregnancy, and worker productivity.

For the majority of NTDs, either there are no treatments or prevention options, or interventions may be prohibitively expensive or difficult to use in low-resource settings.³ For example, traditional diagnostics for African sleeping sickness (human African trypanosomiasis, or HAT) are inadequate, and there are no effective drugs to treat Buruli ulcer or chronic Chagas disease. Projects to develop new or better vaccines, diagnostics, and therapeutics to address these NTDs have historically stalled because they were generally commercially unattractive to multinational pharmaceutical companies.⁴ For example, of the 1,556 new drugs approved between 1975 and 2004, only 21 (1.3 percent) were targeted for tropical diseases and tuberculosis.⁵ Although NTDs account for 11.4 percent of the global disease burden, they disproportionately affect the developing world. Thus, the dearth of products and product development activity targeted to NTDs represents a public health failure.⁶

■ **Global R&D investment.** In recent years, the global landscape for neglected disease research and development (R&D) has improved. A number of public-private product development partnerships have been founded to develop new vaccines, diagnostics, and therapeutics to bridge this global health divide. These include the Drugs for Neglected Diseases Initiative, Institute for One World Health, Infectious Disease Research Institute, and Human Hookworm Vaccine Initiative. The product development partnership strategy brings together public and private actors to harness expertise in health product development and delivery, is often funded by philanthropic organizations, and has been shown to be a cost-effective vehicle for the development of drugs to treat NTDs.^{3, 7, 8} Today most R&D activity for drugs targeted against neglected diseases by multinational drug companies, small and medium-size firms from industrialized countries, and public-sector institutions is carried out in conjunction with a product development partnership.⁸

The first and most comprehensive survey of global investment into R&D for new products for neglected diseases—the G-Finder report—found that just over \$2.5 billion was spent in 2007.⁹ Nearly 80 percent went to the “big three” diseases: HIV, malaria, and TB. The remaining neglected diseases each received less than 5 percent of global funding, and five diseases (leprosy, Buruli ulcer, trachoma, rheumatic fever, and typhoid and paratyphoid fever) received less than \$10 million, or 0.4 percent of total global investment, each.

In aggregate, the private biopharmaceutical industry provided \$231.8 million (9.1 percent of the global total), 80 percent of which came from multinational drug companies and 20 percent came from biopharmaceutical small and medium-size firms. Both types of firms reported that the majority of their R&D for neglected diseases went to the “big three” diseases (75 percent and 82 percent, respectively).

The remaining investment from the biopharmaceutical industry primarily went to so-called commercial neglected diseases, such as dengue, pneumonia, meningitis, and the diarrheal diseases, where neglected disease activity can be piggybacked onto activity targeting commercial markets for these diseases. “Low or no commercial” diseases, such as Chagas disease, leishmaniasis, African sleeping sickness, trachoma, and helminth infections, attracted little to no investment by the firms surveyed. It is worth noting that primarily companies from the developed world were included in the G-Finder survey.

■ **Global product development.** There are bright spots on the horizon for NTDs, including examples of inexpensive, effective, and safe products that are readily available to treat the most prevalent diseases such as schistosomiasis, trachoma, and onchocerciasis.¹⁰ For example, onchocerciasis (river blindness) was brought under control in ten West African countries with the help of Merck’s donation of ivermectin through its Mectizan Donation Program, which celebrated its twenty-year anniversary in 2007. Treatment projections indicate that over eighty-six million people will receive annual treatment with ivermectin through the African Programme for Onchocerciasis Control by 2010.¹¹ In addition, the World Health Organization’s (WHO’s) SAFE strategy (surgery, antibiotics, facial hygiene, and environmental improvements) and Pfizer’s donation of the antibiotic azithromycin helped reduce the incidence of trachoma by eighty-nine million cases from 1997 to 2008. In China, Sri Lanka, and other endemic countries, lymphatic filariasis has been controlled with mass administration to more than one billion people using albendazole and ivermectin donated by GlaxoSmithKline and Merck, respectively.

■ **Emerging-economy firms.** These laudable initiatives are modeled on charity or so-called corporate social responsibility, however, and they are unlikely to be the only sustainable solution to providing preventive and therapeutic interventions for all NTDs. What if there were another source of innovation that was relatively untapped and more affordable that invests in R&D for NTDs and has proven ability to bring products to market? In this paper we argue that there is such a source of innovation: the ongoing R&D activities taking place in emerging economies, particularly within the private sector.

We studied seventy-eight homegrown, small to medium-size, health biotechnology companies in the emerging economies in Brazil, China, India, and South Africa. Purposive sampling (which selects participants with knowledge or expertise in the area being investigated) was used to identify innovative homegrown companies that specialize in the development of biologics, biopharmaceuticals, diagnostics, and related technologies and services, targeted to address domestic needs. We excluded manufacturers of generics and domestic subsidiaries of multinationals. To identify the companies, we consulted local and global experts familiar with the local biotechnology sectors, literature resources, and industry reports. We also asked interviewees about other companies in their country. Although we may have missed a few companies, and the industry situation

changes from year to year, the subsequent reception of our published papers has borne out that this is a reasonable sample of the more innovative domestic firms in these countries.¹²⁻¹⁵

The seventy-eight companies have a collective pipeline of nearly 500 products for more than 100 indications. This pipeline constitutes both novel and other products, about half of which are in development and half have received domestic regulatory approval and are being sold on the domestic market. Some of these products are reaching international markets as well. Many senior managers we interviewed regard local health needs—and, more broadly, NTDs—as viable market entry points. Indeed, emerging-economy companies regard the so-called neglected diseases as business opportunities. Many of the emerging-economy firms we interviewed view innovation and access as intrinsically linked. Their focus includes developing cost-effective health products adapted to local conditions that are also appropriate for the needs of local, poorer markets. By focusing on “affordable innovation,” emerging-economy companies are increasing their market share in emerging and developing countries by providing access to an increasing number of health products for poorer consumers whose needs have typically been ignored or neglected.

In this paper we describe the pipeline of health technologies for NTDs from these seventy-eight emerging-economy companies. We argue that these firms represent potential partners for global health initiatives, and we propose a mechanism—the Global Health Accelerator—to better bring to scale the product development efforts of these emerging-economy firms.

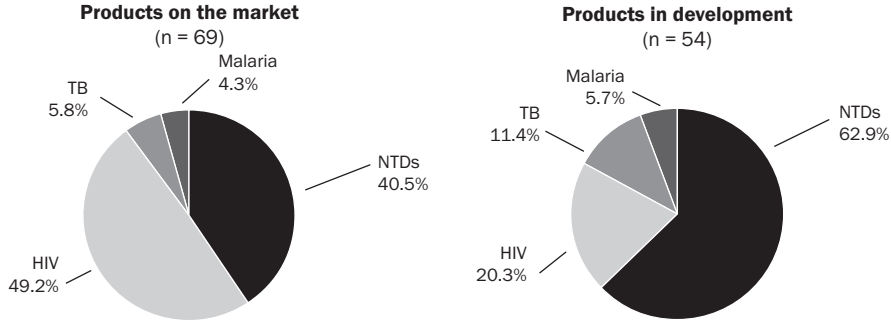
‘Southern’ R&D For Neglected Tropical Diseases

Of the approximately 500 products collectively sold or developed by firms we studied, 123 target “neglected diseases” (NTDs plus the big three): 69 on the market and 54 in development (Exhibit 1). Of the 62 products for NTDs (excluding the big-three diseases), slightly more are in development (34) than are on the market (28) (Exhibits 2 and 3).

■ **Diagnostics.** Diagnostics represent nearly half of the NTD products on the market and nearly 40 percent of those in development (Exhibit 2). The technology used in some of these rapid, point-of-care, or enzyme-linked immunosorbent assay (ELISA) diagnostics may be considered low-tech. However, some of the emerging-economy companies selling them emphasized that diagnostics for NTDs often had to be stable and highly reliable in rural or low-resource areas. Thus, several emerging-economy diagnostic companies have focused on providing affordable diagnostics for the smaller markets typically ignored by larger competitors. For example, FK Biotecnologia (Porto Alegre, Brazil) is developing point-of-care diagnostic testing platforms for Chagas disease, dengue fever, leptospirosis, and syphilis; it is developing tests for schistosomiasis and treponematoses. Vision Biotech (Cape Town, South Africa) is developing rapid diagnostic test platforms for African trypano-

EXHIBIT 1

Products For HIV, Malaria, TB, And Neglected Tropical Diseases (NTDs), On The Market And In Development, In Emerging-Economy Firms, By Type Of Disease, 2009



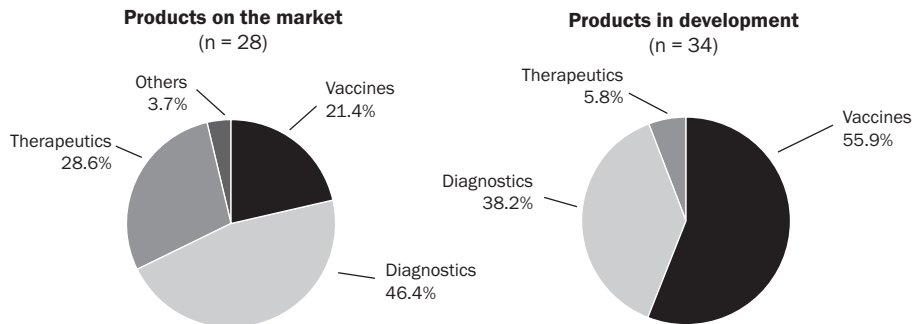
SOURCE: Data compiled from the pipelines of seventy-eight emerging-economy firms based on information originally published in the sources listed in Notes 12–15 in text.

somiasis, schistosomiasis, and dengue fever. Bhat Biotech (Bangalore, India), sells an immunoassay-based rapid test for leishmaniasis and is developing a diagnostic kit for leprosy.¹⁶

■ **Vaccines.** Vaccines represent about 21 percent of the products on the market and more than half of the products in development (Exhibit 2). The vaccine that has reached the market most recently is oral cholera vaccine, ShanChol, which was launched by Shantha Biotechnics (Hyderabad, India) in India in April 2009. The vaccine was developed by the International Vaccine Initiative (Seoul, South Korea) and was licensed to Shantha, which is manufacturing it for less than US\$2 per dose and has 300,000 doses warehoused. ShanChol offers two years of protection against the two strains of cholera bacteria known to cause epidemics, 0139 and 01. This

EXHIBIT 2

Products For Neglected Tropical Diseases (NTDs), On The Market And In Development, In Emerging-Economy Firms, By Type Of Product, 2009



SOURCE: Data compiled from the pipelines of seventy-eight emerging-economy firms based on information originally published in the sources listed in Notes 12–15 in text.

EXHIBIT 3
Emerging-Economy Firms’ Pipelines For Neglected Tropical Disease (NTD) Products,
By Type Of Product (Vaccine, Diagnostic, Therapeutic, Others)

Conservative definition of NTDs	On market				In development			
	Vaccine	Diagn.	Therap.	Others	Vaccine	Diagn.	Therap.	Others
Chagas disease						2		
Human African trypanosomiasis					1	1		
Leishmaniasis			2			1	3	
Leprosy			1			1		
Schistosomiasis						2		
Trachoma (chlamydia)		2						
Extended definition of NTDs								
Cholera	2							
Dengue		3		1	5	2		
Enteric pathogens (shigella, salmonella, <i>E. coli</i>)		1			1			
Giardiasis			1					
Japanese encephalitis	1				6			
Leptospirosis						1		
Rabies	3		4		3	1		
Treponematoses (<i>Treponema pallidum pallidum</i> : syphilis)		7				1		
Others								
Chikungunya					3			
HIV		17	17		3	4	4	
Malaria		3			2		1	
TB	1	1	2			4	1	1
Total	7	34	27	1	24	20	9	1

SOURCE: Data compiled from the pipelines of seventy-eight emerging-economy firms based on information originally published in Notes 12–15 in text.

means that ShanChol offers longer and broader protection than Dukoral, the only internationally licensed oral cholera vaccine on the market. Produced by the Swedish Bacteriological Laboratory, Dukoral costs up to \$6 per dose to manufacture—more than three times the cost to manufacture ShanChol—and retails for around \$50–\$75 in North America. Shantha plans to apply for WHO prequalification, which, if expedited, would make its vaccine available internationally within one year. Experts familiar with ShanChol have expressed optimism that there will be future global-market interest in the vaccine from international purchasers such as the GAVI Alliance, given its broader protection and more affordable price point than Dukoral. Despite this enthusiasm, however, there is no guarantee that an international customer base will surface to pay for ShanChol for poor patients.

Shanghai United Cell Biotechnology Co. Ltd. (Shanghai, China) also manufactures an oral cholera vaccine, OraVacs, which is nearly chemically identical to Dukoral. Whereas Dukoral is an oral suspension that must be reconstituted in water, OraVacs is formulated as an enteric-coated capsule. OraVacs has received

regulatory approval for marketing in China and the Philippines and is being sold primarily to the niche travelers market. At US\$25, its retail price is two to three times cheaper than that of Dukoral.¹⁷ Shanghai United made this vaccine available to the Chinese government at a much lower price on a humanitarian basis after earthquakes hit western China in May 2008. In addition to these cholera vaccines, other vaccines in development, primarily by Indian and Chinese firms, are targeted to chikungunya, a viral disease transmitted to humans via mosquito bites; dengue fever; Japanese encephalitis; and rabies.¹⁶

■ **Therapeutics.** Therapeutics represent about 28 percent of the NTDs products on the market and about 7 percent of the products in development by the seventy-eight emerging-economy firms described here (Exhibit 2). Among the products on the market are two formulations of Amphotericin B for the treatment of human visceral leishmaniasis, including a liposomal version called Fungisome being sold by Lifecare Innovations (Gurgaon, India). Hebron Farmacêutica Ltd. (Recife, Brazil) is selling Giamebil, an extract from the plant *Mentha crispa* (small-leaf mint) that kills infectious amoebae and *Giardia lamblia*, a protozoan parasite that commonly causes diarrheal illnesses. Silvestre Labs (Rio de Janeiro, Brazil) is selling Dermacerium (a formulation of cerium nitrate and silver sulfadiazine), which is a broad-spectrum topical antimicrobial agent used to prevent and treat infection in skin wounds, including those from leprosy. Several companies are also selling anti-rabies immunoglobulin for prophylaxis following exposure to the rabies virus.¹⁶

■ **Overall capability.** The capabilities of the global South to conduct innovative R&D for new product development are much richer than the partial snapshot described here. In addition to the seventy-eight companies we studied, there are many more small and medium-size health biotechnology firms in these countries (more than 500) and in other emerging economies such as Malaysia, Indonesia, and Mexico, as well as research institutes and universities that in some cases also commercialize health products for NTDs. We have not yet expanded our studies to survey the extent to which these additional organizations are developing products for NTDs. As one example, two government-owned vaccine manufacturers in Brazil, the Butantan Institute and Biomanguinhos (part of the Oswaldo Cruz Foundation), each has a sizable in-house product development portfolio for NTDs.

Why 'Southern' R&D For NTDs Matters

For Northern actors developing products for Southern diseases, especially diseases of the poor such as NTDs, a major challenge has been affordability. Northern R&D for NTDs has largely followed a business model where products are developed with the same relatively high costs as for other products in the company, and then donated on a charitable basis. Although laudable, this might not be sustainable. Unlike the companies in the North, the business model of many emerging-economy companies in the South is not charity but affordable innovation. Such firms are keenly aware of the on-the-ground realities of local markets and, as de-

scribed above, have been able to develop products that are more affordable than imports.

Affordable innovation has also been a model used by emerging-economy firms to improve product delivery. The Abhay Clinic model developed by Indian Immunologicals, for example, delivers affordable and safe vaccines for rabies, a disease that is endemic in India, to patients in semiurban and rural areas via nearly 1,500 local clinics.^{13,18} The Abhay Clinic delivery model relies on a network of local general practitioners and pediatricians who provide initial and follow-up vaccination and wound care for bite victims at an affordable price determined by the company. In turn, Indian Immunologicals equips the clinics with refrigerators and ensures that the temperature of its rabies vaccine is kept cold enough during delivery from its manufacturing depots (known as cold-chain delivery). Indian Immunologicals is taking steps to expand its delivery model to provide additional affordable vaccines to poor patients in urban, semiurban, and rural settings in India and has started to expand this model to other developing countries.

It is worth noting that emerging-economy biotechnology companies may redirect their focus away from affordable products for NTDs toward more profitable Western markets as they grow and become larger international players. We have previously proposed that emerging-economy governments should consider adapting the U.S. orphan-drug model to provide incentives to their domestic firms to focus on neglected diseases.¹⁹

Nevertheless, the key implication for the global health community is that emerging-economy firms have the capacity, as well as the proven ability, to develop and deliver innovative products for NTDs. Although we have not done due diligence on all of the products listed above, emerging-economy firms represent a source of innovation for NTDs that is well established and will only improve.

Linking Into ‘Southern’ R&D: Engaging Southern Partners For NTDs

One organization that has worked to engage Southern R&D capacity to develop new treatments for the most neglected diseases is the Drugs for Neglected Diseases Initiative. This initiative was established in 2003 by Médecins sans Frontières (Doctors without Borders) and Institut Pasteur along with four publicly funded research organizations in disease-endemic countries: the Indian Council for Medical Research, the Kenya Medical Research Institute, the Oswaldo Cruz Foundation in Brazil, and the Malaysian Ministry of Health. One of the Drugs for Neglected Diseases Initiative’s objectives is to use and strengthen capacities in disease-endemic countries via R&D networks built on North-South and South-South collaborations.

The Drugs for Neglected Diseases Initiative successfully delivered two combination antimalarial products, one with Sanofi-Aventis in 2007 and one with Brazil’s Farmanguinhos in 2008. The initiative is currently developing new treat-

ments for sleeping sickness, leishmaniasis, Chagas disease, and malaria. Its objective is to deliver six to eight new treatments and a robust R&D pipeline for additional new medicines by 2014. Working in partnership with industry, academe, and nongovernmental organizations (NGOs), the initiative has built one of the largest R&D portfolios for NTDs and has seven clinical/postregistration and four preclinical projects under way.

In an interview, Bernard Pécoul, chief executive officer of the Drugs for Neglected Diseases Initiative, confirmed that the focus on Southern R&D was critical to the initiative's model and has played out in practice in board membership and partnerships. He emphasized the importance of partnerships with disease-endemic countries and of stimulating government leadership on NTDs in those countries. A concrete example of a partnership with an emerging-economy firm is the partnership with Advinus (Bangalore, India), which is conducting lead selection in the initiative's visceral leishmaniasis R&D program.

The initiative's model of working with Southern partners may be applicable to other product development partnerships. Given their mandates to develop affordable products for diseases of poverty, these partnerships require partners that can help them deliver on this goal. Indeed, some are now viewing local partnerships as the most cost-effective method of developing products. However, in addition to "pushing" R&D pipelines through product development partnerships, there is an opportunity to "pull" existing R&D efforts in emerging-economy companies so that they might have greater market reach.

The Global Health Accelerator

As illustrated above, emerging-economy companies already have NTD products on the market and in their development pipelines. They also have capacity to develop new products using an affordable innovation model. At present, the tremendous entrepreneurial creativity of the South is not making the full contribution it could to create, commercialize, and distribute health solutions for the world's poor. Many creative and industrious minds, working to bring new products and services to market, face an uphill battle. Although firms are good at serving local markets, a critical bottleneck is their ability to get their products to distant markets where those products are needed by the poor. What is the best way to assist these firms?

Notwithstanding the excellent efforts of the Drugs for Neglected Diseases Initiative and other product development partnerships to reach out to Southern partners, the innovative capacity of emerging-economy firms could be better harnessed. The partnerships are understandably looking for partners for their specific pipeline products, instead of starting with the opportunities available in the pipelines and products of emerging-economy firms. In the case of the Drugs for Neglected Diseases Initiative, the focus is on drugs, and in other product development partnerships related to NTDs, on specific drugs or vaccines; as we have seen,

the pipelines and products of emerging-economy firms also heavily feature diagnostics. The original Southern partners of the Drugs for Neglected Diseases Initiative are research institutes rather than companies, although as the Advinus example shows, there have also been partnerships with companies. In short, there is scope to increase the R&D partnering efforts working in close cooperation with product development partnerships. For this, as well as other services described below, we propose the creation of a Global Health Accelerator.

The accelerator would go well beyond R&D partnerships. Often extremely good at penetrating local markets, many small firms in emerging economies lack expertise in a suite of international business issues—such as understanding regulatory environments, assessing markets, positioning products (including pricing and competitive intelligence), identifying distribution channels (including details of the purchasing decision), accessing financing, and identifying international commercialization partners. These core functions would likely become a central feature of the Global Health Accelerator, as it helps emerging-economy companies expand into other emerging- and developing-country markets where their NTD products are needed.

The accelerator’s mission would be to help Southern firms get their products for neglected diseases to market. It would aim to connect a diverse international community of innovators focused on Southern diseases through a virtual platform (similar to Innocentive’s successful open innovation model) that is greatly useful to those commercializing health products. The Global Health Accelerator would be based in a not-for-profit organizational structure that would be an independent hub among companies, investors, and partners. It would be governed by a board of directors representing its stakeholders and user community. The not-for-profit would behave as a facilitator, not an investor, thereby ensuring its independence and enabling the accelerator to be open to new directions based on the emergence of Southern innovation over time. It would work in close collaboration with product development partnerships. The Global Health Accelerator would not target a particular drug or disease. Rather, it would target innovation with a global health impact.

The accelerator model would include four core elements: business support services; an annual global prize; access to financing and venture capital; and knowledge resources and networking.

■ **Business support services.** The Global Health Accelerator would bring together an active network of the world’s most reputable consulting, accounting, and business planning firms to provide pro bono consulting support to leading proponents of global health innovations in developing and emerging economies. For example, these resources could be used to identify business models for selling products in developing countries that address issues of market penetration, remuneration structures, and sustainability, as well as feasibility across different geographic regions. In contributing to pro bono projects, top-tier consulting firms look for projects requir-

ing strategic thinking that have high-impact potential and reliable partners, and that are exciting and contribute to their employees' development and sense of job satisfaction.²⁰ Firms would also want to participate to associate themselves with the accelerator's charitable mission and its outstanding source of contacts with firms in fast-growing emerging economies.

■ **Global Health EnterPrize.** An annual prize, the Global Health EnterPrize, would recognize new diagnostics, drugs, vaccines, or devices with global health impact developed by Southern companies. This prize could be a powerful tool to attract and inspire Southern health innovators and draw attention to Southern firms possessing important and creative health solutions. In contrast to prizes that identify a specific target, such as the X prize for TB diagnostics, the Global Health EnterPrize would not pre-specify the technology but would invite a wide range of emerging-economy firms making a difference in NTDs to apply.

■ **Access to financing and venture capital.** The partners in the Global Health Accelerator could also use their networks to link to funding agencies, foundations, development finance institutions, private individuals, and venture capitalists interested in providing financing to innovative Southern companies. Securing private financing, particularly risk capital, remains a major challenge in emerging economies. There is no efficient global pipeline of Southern R&D investments for venture capitalists to consider. Access to international investment opportunities, particularly those vetted through the Global Health EnterPrize for Southern R&D, would be an incentive for international investors to participate in the accelerator. Venture capitalists should be interested because the accelerator would represent a source of deal flow from Southern companies that otherwise would have been hard to get access to efficiently. For example, India's Shantha Biotechnics was started with private capital, grew on retained earnings, was acquired in 2006 by the Merieux Alliance (Lyon, France), and was recently sold to Sanofi-Pasteur for \$784 million. Although public development finance institutions such as the World Bank might support the Global Health Accelerator platform, their private-sector arms, such as the International Finance Corporation or the private-sector window of the African Development Bank, might join the accelerator as potential early investors to prove the model and remove risk from the investments of others.

■ **Knowledge resources and networking.** The Global Health Accelerator would feature a resource center whereby accumulated knowledge, such as the pipeline of products for neglected diseases as described above, information on regulatory systems and intellectual property regimes, and case studies of success and failure in developing health products for the poor, could be made publicly available and used by accelerator participants.

■ **Other models.** There are models in other sectors for the Global Health Accelerator to learn from. The Clean Tech Open (<http://www.cleantechopen.com>) is a nonprofit organization dedicated to the development of clean technology startups. It comprises entrepreneurs, academics, investors, and private companies. Its pri-

mary mission is “to act as an innovation catalyst”; to that end, the organization provides resources, mentoring, workshops, and an annual business competition. The initiative has been under way since 2006, and the organization reports that 80 percent of the teams that have availed themselves of Open’s programs are viable businesses and have secured more than \$130 million in funding.

Another relevant example that could inform development of the Global Health Accelerator is the TATA NEN Hottest Startup Awards (<http://www.hotteststartups.in>), a partnership between TATA, a major Indian conglomerate, and the National Entrepreneurship Network (NEN), a not-for-profit dedicated to entrepreneurial education. Winners receive free publicity and advertising, business education, information technology services, guidance and mentorship, and exposure to venture capitalists and relevant multinational corporations.

Although these models focus on startups, and the Global Health Accelerator would focus on extending the reach of existing companies, the activities necessary to support that are comparable enough that these entities offer useful models.

■ **Other approaches.** How might other recent initiatives to stimulate innovation in global health—such as priority-review vouchers, advance-market commitments, and patent pools—foster Southern enterprise development in fighting NTDs?

Priority-review vouchers. Priority-review vouchers enable a company to register a global health product at the U.S. Food and Drug Administration (FDA) and gain expedited approval for another product. Vouchers could result in substantial financial gains to a multinational company that has blockbuster products to register, but they might not be well suited to an emerging-economy company lacking another product for which it seeks approval. Although the emerging-economy company could sell this right and raise cash, the firm might not be focused on gaining FDA approval for its NTD products.

Advance market commitments. Advance market commitments provide incentives to companies to develop a specific product by in effect guaranteeing future purchases of the product. To date, only one such arrangement has been announced, for pneumococcal vaccine. Yet many emerging-economy firms might lack the financing needed to develop a product for the delayed reward of a guaranteed market if they win the race.

Patent pools. In March 2009 GSK announced that it would be donating intellectual property to target NTDs to a patent pool, and in July 2009 Alnylam Pharmaceuticals joined the patent pool as well. This donated intellectual property may help emerging-economy companies develop new products for NTDs. Some useful synergies could arise among patent pools and the Global Health Accelerator concept. For example, access to the patent pool could be facilitated as an additional service of the accelerator.

Ultimately, the accelerator could become “the number to call” for firms in both the North and South interested in entering Southern markets, by providing access

to strategic intelligence and local networks of partners, including innovative companies in the South.

Concluding Comments

As noted, a number of companies in emerging economies are developing and marketing health products for NTDs. This growing sector provides a largely untapped opportunity to advance global health. We have proposed a Global Health Accelerator to help bring these efforts to scale. The accelerator would complement and work in close partnership with existing approaches (such as the Drugs for Neglected Diseases Initiative).

Who might be interested in moving the Global Health Accelerator concept forward? Organization for Economic Cooperation and Development (OECD) governments, which provided US\$1.6 billion in global R&D funding for neglected diseases in 2007,¹⁰ might be interested in the pipeline of products from emerging-economy firms. Developing-world governments will be interested in affordable health products for their populations. Emerging-economy governments will be interested because of both access to health products and the economic development of their companies. Multinationals will be interested both because they are looking for channels to address global health and because they are scouting partners in emerging economies. Finally, philanthropies and international development agencies will be interested because they can make enabling investments that unleash the power of the private sector in the developing world.

In 2007 Bill Gates described the need for “creative capitalism” to address the health problems of the poor.²¹ Creative capitalism relies on global talent, and at the moment much talent in the developing world is underutilized. The Drugs for Neglected Diseases Initiative model has been an important step forward. The Global Health Accelerator, or a comparable model, could help bring Southern biotechnology companies more fully into the global effort to tackle diseases of the poor. Creative capitalism will necessarily involve biotechnology companies in the developing world, which are innovating close to the health problems with an up-front, firsthand focus on affordability and access.

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NOTES

1. Department of Control of Neglected Tropical Diseases. Neglected tropical diseases, hidden successes, emerging opportunities [Internet]. Geneva (Switzerland): World Health Organization; 2006 [cited 2009 May 12]. Available from: http://whqlibdoc.who.int/hq/2006/WHO_CDS_NTD_2006.2_eng.pdf
2. Hotez PJ, Molyneux DH, Fenwick A, Kumaresan J, Sachs SE, Sachs JD, et al. Control of neglected tropical diseases. *N Engl J Med*. 2007;357(10):1018–27.
3. Widdus R, White K. Combating diseases associated with poverty: financing strategies for product development and the potential role of public-private partnerships [Internet]. Geneva (Switzerland): Initiative on Public-Private Partnerships for Health; 2004 Aug [cited 2009 Sep 15]. Available from: <http://www.globalforumhealth.org/content/download/394/2322/file/s14800e.pdf>
4. Trouiller P, Olliaro P, Torreele E, Orbinski J, Laing R, Ford N. Drug development for neglected diseases: a deficient market and a public-health policy failure. *Lancet*. 2002;359(9324):2188–94.
5. Chirac P, Torreele E. Global framework on essential health R&D. *Lancet*. 2006;367(9522):1560–1.
6. Trouiller P, Torreele E, Olliaro P, White N, Foster S, Wirth D, et al. Drugs for neglected diseases: a failure of the market and a public health failure? *Trop Med Int Health*. 2001;6(11):945–51.
7. Morel CM, Acharya T, Broun D, Dangi A, Elias C, Ganguly NK, et al. Health innovation networks to help developing countries address neglected diseases. *Science*. 2005;309(5733):401–4.
8. Moran M. A breakthrough in R&D for neglected diseases: a new way to get the drugs we need. *PLoS Med*. 2005;2(9):e302.
9. Moran M, Guzman J, Ropars AL, McDonald A, Sturm T, Jameson N, et al. Neglected disease research and development, how much are we really spending? [Internet]. London (U.K.): George Institute; 2008 [cited 2009 Sep 15]. Available from: http://www.thegeorgeinstitute.org/shadomx/apps/fms/fmsdownload.cfm?file_uid=409DIEFD-BF15-8C94-E71C-288DE35DD0B2&siteName=iih
10. Global Network for Neglected Tropical Diseases. Disease-specific achievements [Internet]. Washington (DC): Global Network; [updated 2009 Jun 29; cited 2009 Jun 16]. Available from: <http://www.globalnetwork.org/what-we-do/success-stories/disease-specific-achievements>
11. Thylofors B, Alleman M. Towards the elimination of onchocerciasis. *Ann Trop Med Parasitol*. 2006;100(8):733–46.
12. Al-Bader S, Frew SE, Essajee I, Liu VY, Daar AS, Singer PA. Small but tenacious: South Africa's health biotech sector. *Nat Biotechnol*. 2009;27(5):427–45.
13. Frew SE, Rezaie R, Sammut SM, Ray M, Daar AS, Singer PA. India's health biotech sector at a crossroads. *Nat Biotechnol*. 2007;25(4):403–17.
14. Frew SE, Sammut SM, Shore AF, Ramjost JK, Al-Bader S, Rezaie R, et al. Chinese health biotech and the billion-patient market. *Nat Biotechnol*. 2008;26(1):37–53.
15. Rezaie R, Frew SE, Sammut SM, Maliakkal MR, Daar AS, Singer PA. Brazilian health biotech—fostering crosstalk between public and private sectors. *ure Biotechnol*. 2008;26(6):627–44.
16. Supplemental Exhibits 1 and 2 provide more detail on these developments; they are available online at <http://content.healthaffairs.org/cgi/content/full/28/6/1760/DC1>.
17. Shanghai United Biotech. OraVacs [Internet]. Shanghai (China): Shanghai United Biotech; [updated 2009; cited 2009 Jun 21]. Available from: <http://e.unitedbiotech.com.cn/en/EnProduct-OCV-general.asp>
18. World Health Organization. World Health Organization Global Health Atlas [Internet]. Geneva (Switzerland); WHO; [updated 2007; cited 2009 Aug 9]. Available from: <http://apps.who.int/globalatlas/dataQuery/default.asp>
19. Frew SE, Kettler HE, Singer PA. The Indian and Chinese health biotechnology industries: potential champions of global health? *Health Aff (Millwood)*. 2008;27(4):1029–41.
20. Boston Consulting Group. Making a difference—BCG and its pro bono clients [Internet]. Boston (MA); BCG; 2004 [cited 2009 Sep 21]. Available from: <http://www.bcg.com/documents/file14459.pdf>
21. Gates B. 2007 Harvard commencement: Bill Gates [Internet]. Seattle (WA): Bill & Melinda Gates Foundation; [updated 2007 Jun 6; cited 2009 Jun 16]. Available from: <http://www.gatesfoundation.org/speeches-commentary/Pages/bill-gates-2007-harvard-commencement.aspx>